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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/564,674
Filing Date: July 14, 2006
Appellant(s): WIJLAARS ET AL.

William H. Logsdon
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 11, 2010 appealing from the Office action mailed January 29, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Kou et al. Modeling drug release from dynamically swelling poly(hydroxyethyl methacrylate-methacrylic acid) hydrogels. Journal of Controlled Release 1990 12:241-250.

Malmonge et al. Artificial articular cartilage: mechanoelectrical transduction under dynamic compressive loading. Artificial Organs 2000 24:174-178.

Pissis et al. Poly(hydroxyethyl acrylate) – nylon 6 nanocomposites. Dielectric and water sorption properties. Proceedings of the 10th International Symposium on Electrets 1999 p561-564.

Slivka et al. Porous, resorbable, fiber-reinforced scaffolds tailored for articular cartilage repair. Tissue Engineering 2001 7:767-780.

Young et al. high-strength, ultra-thin and fiber reinforced pHEMA artificial skin
Biomaterials 1998 19:1745-1752.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-9 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. (previously cited) in view of Slivka et al. (previously cited), Pissis et al. (previously cited) and Young et al. (previously cited).

Malmonge et al. teach a copolymer of 2-hydroxyethyl methacrylate (HEMA) and acrylic acid (AA) as artificial articular cartilage in a joint prosthesis (see page 175 column 1 paragraph 2-3; instant claims 8, 9, and 14). They go on to teach that the hydrogels made of this material have negative (ionized) groups fixed within the macromolecular network that are believed to participate in the compressive strength of the material (see page 174 column 2 paragraph 1 line 15-page 175 column 1 line 5 and page 175 column 1 paragraphs 2-3; instant claim 8). Ionized groups were therefore added to the hydrogel prior to polymerization and were present after polymerization (see page 176 column 1 paragraph 1; instant claim 8). Malmonge et al. also teach the ratio of HEMA to AA in the polymer to be 97.5 to 2.5 as well as 95 to 5 (see page 175 column 1 paragraph 4; instant claim 8). Malmonge et al. do not teach whether this ratio is based upon mass or moles. In the case where the ratio described the molar balance, the corresponding mass percentage of AA in the polymer would be 1.8% (mass percentage corresponding to 2.5 mol%) and 3.6% (mass percentage corresponding to 5

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mol%), as calculated by the examiner. Further, Malmonge et al. also teach the hydrogel being soaked (saturated) in a liquid solution (see figure 1 and caption; instant claim 12).

Malmonge et al. do not teach the incorporation of fibers into the taught hydrogel.

Slivka et al. teach a fiber reinforced gel structure for articular cartilage repair. Other known repair materials are taught to frequently lack mechanical properties to ensure long term efficacy and could lead to inadequate support during healing (see page 767 paragraph 1). Specifically, Slivka et al. teach that a polymer solution is combined with polymer fibers sized at 2.5 mm in length such that a gel was formed (see page 770 paragraph 1). The fibers are taught to be present at 5%, 10%, 15%, and 20% (see figure 2). As the fiber loading increased, the compressive modulus and yield strength increased, indicating an improvement in mechanical properties due to the presence of these fibers (see figure 7). In addition, Slivka et al. point to the 10% fiber loading as particularly good for its slightly higher stiffness as compared to native tissue (see page 778 paragraph 1).

Pissis et al. teach the incorporation of Nylon particles (fibers), a swellable polyurethane, into a poly(hydroxyethyl acrylate) hydrogel (see page 561 paragraph 1; instant claims 8 and 13). Pissis et al. also teach that all polymer hydrogels would benefit from having their mechanical properties improved and that the inclusion of the Nylon serves this purpose (see page 561 paragraph 1; instant claims 8 and 13). Further Pissis et al. teach the inclusion of the Nylon particles at 10% (see page 561 paragraph 2 lines 17-18; instant claims 8 and 13).

Young et al. teach a fiber reinforced polyHEMA as a biomaterial (see abstract and page 1745 column 2 lines 6-13). Specifically Young et al. teach that due to the capability of hydrogels to absorb large amounts of water, their polymer networks and mechanical strength can be compromised in the process (see page 1745 column 1 lines 7). Young et al. go on to teach fiber reinforcement, the inclusion of fibrous material within the hydrogel, to improve the mechanical properties of these otherwise very versatile materials (see page 1745 column 1 line 18-column 2 line 5). Further, Young et al. teach a nylon and elastic spandex fiber mesh as one utilized fiber reinforcement (see page 1746 column 1 lines 10-14 and figure 2). As demonstrated by the microscopic images provided, the fibers in this mesh were longer than one millimeter (see figure 2 panel c and panel d); instant claim 8)

Slivka et al. explicitly teach the inclusion of polymer fibers of at least one millimeter in length at 10% to 70% in a gel construct to improve its mechanical properties, which like Malmonge et al., is intended for articular cartilage repair. Therefore one of ordinary skill in the art would have been motivated to apply the same approach to improve the gel of Malmonge et al. since it also requires mechanical strength and integrity to function for its intended purpose as articular cartilage. Since both Pissis et al. and Young et al. teach fiber reinforcement in hydroxylated acrylate based hydrogel medical devices and Young et al. specifically teach their ability to mechanically reinforce such structures, it would have been obvious to one of ordinary skill in the art at the time of the invention to embed a fiber mesh, as taught by Young et al., in the HEMA—AA hydrogel prosthesis of Malmonge et al. Further, since both Slivka

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et al. and Pissis et al. provide a known proportion of gel to mesh in such devices and Young et al. provide known varieties and dimensions of mesh used to reinforce hydrogels in biomaterials, one of ordinary skill would have also found it obvious to embed nylon/spandex fibers longer than one millimeter and composing approximately 10% of the hydrogel composite in the hydrogel composition of Malmonge et al. (applying a known technique to a known device ready for improvement to yield a predictable result/ use of known technique to improve similar devices in the same way). Consequently, the saturation of the Slivka et al., Pissis et al., and Young et al. modified gel of Malmonge et al. would also have the swellable nylon/spandex fibers saturated as well (see Malmonge et al. figure 1 and caption; instant claim 12).

Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. are silent in regards to the spandex fibers "sucking up" monomer solution. Two methodologies of preparing fiber reinforced gels are presented by the cited references, one of which is set forth for hydrogels in particular. Young et al. and Pissis et al. both teach the preparation of their composite hydrogels by the combination of reinforcing fibers/particles along with monomer solutions that include cross-linker and initiator followed by polymerization of the monomer to yield the final fiber reinforced hydrogel. Since urethane and carboxyl chemical groups are well known to form hydrogen bonds, one of ordinary skill in the art would reasonably expect such an association to occur in the unpolymerized mixture of HEMA, AA, and spandex fibers made obvious by the Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. This association can be termed "sucking up" of the acrylic acid monomer solution (see instant claims 8 and 15). Moreover, applicants

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exemplify spandex fibers, specifically, as the envisioned polyurethane reinforcing fiber that has this property of “sucking up” monomer solutions of HEMA and/or sodium methacrylate upon immersion (see instant specification page 1 lines 18-21, page 2 lines 1-2 and page 3 lines 1-3). Thus the fiber-reinforced matrix as claimed composed of HEMA-AA with spandex fibers made obvious by Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. would also include a monomer solution “sucked up” by the fibers. Therefore claims 8-9 and 12-15 are obvious over Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al.

Claims 8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. as applied to claims 8-9 and 12-15 above, and further in view of Kou et al. (previously cited).

The teachings of Malmonge et al. in view of Slivka et al., Pissis et al. and Young et al. make obvious a HEMA-AA hydrogel with 10% Nylon/spandex fibers (dry weight), such that the AA content was from 1-5% (dry weight). However, this modified reference does not teach the use of methacrylic acid (MA) in the hydrogel.

Kou et al. teach a HEMA-MA hydrogel as being known in the art at the time of invention (see page 241 column 1 paragraph 1; instant claims 8 and 10). Further, the MA only differs from the AA in that it has an additional methyl group in the place of a hydrogen atom. Thus in a hydrogel, HEMA-MA would have negative groups fixed within its macromolecular network like HEMA-AA. “Compounds which are position isomers (compounds having the same radicals in physically different positions on the same

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nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers prima facie obvious).” In addition, the MPEP cites Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214 and states that, “Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.” (see MPEP 2144.08). It would therefore be obvious to one of ordinary skill in the art at the time the invention was made to employ HEMA-MA in place of the HEMA-AA taught by Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. It also would have been obvious for one of ordinary skill in the art to pursue known options within their technical grasp and use HEMA-MA instead of HEMA-AA in the Slivka et al., Pissis et al., and Young et al. modified hydrogel of Malmonge et al. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the monomer ratios taught by Malmonge et al. where MA replaces AA. Therefore claims 8 and 10 are obvious over Malmonge et al. in view of Slivka et al., Pissis et al., Young et al., and Kou et al.

(10) Response to Argument

The Appellant contends that an error was recognized by the Examiner in the rejection made over Malmonge et al. in view of Pissis et al. and Young et al. based upon the declaration provided by Huyghe. This contention is not accurate. The rejection was strengthened by the addition of Slivka et al. to indicate that the addition of fiber reinforcements to cartilage repair structures was not just a logical step based upon the general knowledge of the desired properties of cartilage substitutes and hydrogel mechanics but was a known approach that had been previously utilized for imparting added structural integrity in these particular devices. Neither the Appellant's arguments presented through the course of prosecution nor the declaration provided by Huyghe have been persuasive in demonstrating the non-obviousness of the instant invention. Moreover, contrary to the Appellant's argument the Examiner never agreed that the instantly claimed invention was not obvious over Malmonge et al. in view of Pissis et al., Kou et al. and/or Young et al.

The Appellant argues that Malmonge et al. do not teach providing mechanical strength and toughness to a hydrogel. It is noted that mechanical strength and toughness in a hydrogel are not features that are recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. While the Appellant also notes that the incorporation of a fiber into a hydrogel, the length of the fiber, the use of 10-70% (m/m) of the fiber, and the uptake of a monomer is not taught by Malmonge et al., these limitations are met by the combined teachings of Slivka et al., Pissis et al., and Young et

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al. The Appellant goes on to point out teachings that are not provided in each of these references such as Pissis et al. lacking a teaching of fibers having a length of a millimeter or greater being incorporated in a gel. Both Slivka et al. and Young et al. teach reinforcement fibers in a gel that are greater than one millimeter in length as well as the benefit that fiber reinforcement provides to the mechanical properties of gels. The Appellant goes on to argue that Pissis et al. teach the inclusion of nanoparticles in a hydrogel at a maximum of 10% by weight then argue that Pissis et al. does not teach incorporation of fibers in a hydrogel at 10-70% (m/m). There is no size minimum detailed in the instant application in order for a material to be considered a "fiber." Therefore the teaching of a 10% loading of nanoparticles in the hydrogel of Pissis et al. meets the claim limitations of a hydrogel with fibers at 10-70% (m/m). When combined with Malmonge et al., these teachings render obvious a polymerized hydrogel with 10% m/m fiber. The teachings of Slivka et al. further support such fiber reinforcement density in their teachings of a fiber reinforced artificial articular cartilage with a 10% m/m fiber loading where the fibers are greater than one millimeter in length. Moreover, Young et al. also teach a fiber reinforced gel material for biological use that employs fibers greater than one millimeter in length to improve its mechanical integrity and function demonstrating that not only was a 10% loading known for reinforced hydrogels in general, but specifically in the context of hydrogels utilized for biological applications as replacement tissues. Thus the full set of combined references meet the limitations of a polymerized gel with fibers at 10-70% (m/m) that are greater than one millimeter in length. The Appellant's piecemeal argument pointing out the deficiencies of a subset of

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these cited references cannot show nonobviousness since the rejections are based on a larger combination of references.

In additional remarks regarding Pissis et al., the Appellant argues that this reference also lacks teachings of Nylon nanoparticles imparting mechanical strength and toughness to the hydrogel. It is again noted that mechanical strength and toughness in a hydrogel are not features that are recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

The Appellant further argues that Young et al. when combined with Malmonge et al. and Pissis et al. does not render obvious the use of 10-70% (m/m) fibers. As discussed above, the teachings from these references does in fact render this limitation obvious. More importantly, the rejection is based upon a larger set of references and for this reason the appellant cannot show non-obviousness by arguing against a subset of those cited.

Concerning the teachings of Slivka et al., the Appellant argues that they do not teach the swellability properties or load bearing capacity of a swollen hydrogel in a water-salt environment. Swellability of the fibers in the structure of the invention is the only one of these limitations that is recited in a claim. While the full combination of references is silent to this property, fibers made of nylon or spandex as taught, whose inclusion in the hydrogel of Malmonge et al. is obvious from the full cited combination of references, are the same materials the Appellants suggest in the instant disclosure as the monomer swellable fibers. Since they are the same material as that explicitly

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envisioned and suggested by the appellant, the nylon or spandex fibers must also have the same swellability properties.

The Appellant argues that the teachings of Pissis et al. are in contrast to the contention that the nylon or spandex fibers in the composition material made obvious by Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. would "suck up" the monomer solution claimed in the preparation of the claimed polymerized hydrogel that is also made obvious by this set of references. This argument is based upon a teaching by Pissis et al. that swelling is due to water sorption being confined to the hydrogel phase which does not contain reinforcing material. The claim limitation and this discussion are two entirely different instances in time. The claims' limitation of "said swellable fibers have sucked up at least one monomer solution prior to polymerization of the hydrogel" is a limitation regarding the behavior of the fibers while the composite material is being constructed before the hydrogel has polymerized. The teaching that the appellant references in Pissis et al. regards the behavior of the fully constructed composite after the hydrogel has been polymerized with the incorporated fibers. Therefore Pissis et al. do not teach away from their nylon fibers "sucking up" monomer solution prior to polymerization. Additionally, Pissis et al. explicitly teach combining their nanoparticle fibers with monomer solution and subsequently polymerizing the monomer (see page 561 paragraph 2). Thus the nanoparticles are in fact soaked with monomer solution, contrary to the Appellant's argument.

In addition, the Appellant argues that Young et al. teach incorporating the fibers after the PHEMA membrane is polymerized. Young et al. teach that the reinforcing

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fabrics are embedded in the membrane (see page 1748 column 2 line 2-3). While the Appellant contends that the teaching of Young et al. that, “for manufacturing the composite fiber reinforced PHEMA membranes three types of commercial fabrics....were added into the membranes as reinforcing networks,” means the fabrics were added after polymerization; their preparation of a membrane involved combining the constituent components, which include the fibers, and then polymerizing the gel. Young et al. teach the removal of the reinforced composite from a mold, implying the reinforcing fibers are included in the mold along with the unpolymerized components for the hydrogel. There is no suggestion that any post-polymerization technique was utilized to incorporate the reinforcing fibers into a pre-formed membrane. Therefore Young et al. do not teach incorporating the fibers after the PHEMA membrane is polymerized and their reinforcing fibers would be soaked in monomer and have “sucked up” monomer prior to polymerization.

The Appellant then argues that there was no reason to use nylon particles larger than nanometers in size because Pissis et al. teach particles on a nanometer size scale and Slivka et al. teach millimeter scale particles that are polyglycolide and not polyamide like nylon. Nanometers are merely a dimension as are millimeters. Thus the same particle can be described on a nanometer scale as well as on a millimeter scale. There is no consistent interpretation of the limitation of size connected to the terminology “nanoparticle.” Pissis et al. refer to their particles as nanoparticles, but do not measure their size. Additionally, Pissis et al. do not provide any teachings that explicitly direct the artisan of ordinary skill away from particles that are larger than those

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they employ. In fact, Pissis et al. provides general teachings about the need for the improvement of mechanical properties in hydrogels utilized in medicine and exemplify one type of fiber reinforcement to reach this end. While the Appellant characterizes the rejection as “picking over” the teachings of Pissis et al., the Appellant neglects to address the teachings of Young et al. in motivating the selection of particles larger than one millimeter in length to reinforce the hydrogel of Malmonge et al. Young et al. explicitly teach fiber reinforced HEMA based gels with nylon or spandex fibers that exceed one millimeter in length for materials intended for biological applications, as is the intent of Malmonge et al. The Appellant suggests that there was no reason to consider polyamide fibers greater than one millimeter and that the references do not teach such an embodiment; however, Young et al. clearly show such a fiber as a reinforcement in a HEMA based hydrogel in panels c and d of figure 2, where nylon containing fibers are shown in their composite. The presence of such fibers were demonstrated by Young et al. to improve the mechanical properties of the hydrogel and for this reason such fibers would have been obvious to include in the hydrogel construct of Malmonge et al. to also improve its mechanical properties. Additionally, Young et al. and Slivka et al. teach that fibers sized greater than one millimeter can be used to reinforce gels that are used to approximate biological tissue. Because this particular size had been employed in this capacity and the hydrogel of Malmonge et al. is also intended to approximate biological tissue, the use of this size of fibers in the hydrogel of Malmonge et al. would have been obvious even when considered along with the teachings of nanoparticle reinforcement fibers by Pissis et al.

The Appellant also argues that there was no reason to use more than 10% nylon fibers in a hydrogel. In these statements the Appellant contends that Pissis et al. warn against utilizing more than 10% fiber loading; however, Pissis et al. make no such warning. Pissis et al. teach the limitation that their polymer formulation makes on the amount of nanoparticles fibers that can be included in their hydrogel because of their desire to have 40% water in the gel and the fact that the nanoparticles were provided as a suspension (see page 561 paragraph 2). Such limitations were not present in the polymer formulation in the artificial articular cartilage of Malmonge et al. or Slivka et al. Since Slivka et al. teach four fiber loading levels and pinpoint the 10% loading level as performing particularly well in their experiments and in those of others for artificial articular cartilage, it would have been obvious to follow these teachings and add this quantity of fiber reinforcement to the hydrogel based artificial cartilage of Malmonge et al. (see page 778 paragraph 4). Moreover the nylon fibers had been shown to function as reinforcing fibers in gels that approximate biological tissue where the presence of fibers improved the mechanical function of the gel (see Young et al.) For this reason there would have been a reasonable expectation that nylon fibers in a HEMA based gel for artificial cartilage would also improve the mechanical properties of the gel and improve its ability to function as cartilage. While Young et al. may teach using a lower proportion of fibers, the application of their product as skin does not require the same degree of strengthening as that of Malmonge et al. and Slivka et al. which are used as load bearing cartilage.

Contrary to the Appellant's argument, the references do not teach away from the instant invention where fibers composed of nylon are present at 10% in the hydrogel of Malmonge et al. Taken as a whole the references lead the artisan of ordinary skill to such a product in spite of some examples that detail a lower fiber loading. There are no explicit teachings away from a fiber loading of 10% or greater when the hydrogel is utilized as articular cartilage or when it has the composition as taught by Malmonge et al.

The Appellant additionally discussed the declaration filed by Huyghe touting its experiments as a comparison between a hydrogel similar to that of Malmonge et al. and the instant invention where that of the instant invention had superior properties. The experiment in exhibit B provided by the declaration shows that the mechanical integrity of a fiber reinforced hydrogel after having been subjected to loading is better than that of an unreinforced gel. This result is the expected outcome from the utilization of a fiber reinforcement in a hydrogel and was well known at the time of the invention. Young et al. demonstrate a similar phenomenon in their stress strain analysis of their unreinforced HEMA (P2) and nylon reinforced HEMA (S2). Here figure 3b shows that the unreinforced gel breaks at 3% strain while the nylon reinforced gel breaks at 400%. The other experiment provided by Huyghe in exhibit C demonstrates the ability of nylon fibers to absorb the monomer solution utilized to prepare PHEMA. This is merely a property of the nylon itself and in no way distinguishes the instant invention from that made obvious by Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al.

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The Appellants do not provide arguments disputing the obviousness of the instant invention over Malmonge et al. in view of Slivka et al., Pissis et al., Young et al., and Kou et al. Therefore the invention of the instant claims is obvious over Malmonge et al. in view of Slivka et al., Pissis et al., Kou et al, and/or Young et al.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Caralynne Helm/
Examiner, Art Unit 1615

Conferees:

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615

/Kay Kim/
Primary Patent Examiner